Fanttest®

Chlamydia & Gonorrhoea Rapid test (For Female) Instruction for Use

INTENDED USE

The Chlamydia & Gonorrhoea Rapid test (For Female) is an in vitro immunochromatographic assay for the qualitative detection of antigens in vaginal swab specimens self-collected by female patients against the Chlamydia and Gonorrhoea infection. This test is intended for use as an aid in the diagnosis of Chlamydia and Gonorrhoea infections in symptomatic and asymptomatic females.The test is intended to be used by laypersons as a self-test.The test can be performed by individuals older than 18 years.

SUMMARY

Chlamydia: Chlamydia trachomatis (Ct) represents a bacterial pathogen with the capacity to infect various anatomical sites, including the eye, reproductive tract, and other organs. It plays a significant role in the development of conditions such as urethritis and cervicitis. Primarily affecting the young adult population, Ct exhibits an incubation period ranging from several days to several months, typically averaging 1 to 3 weeks. Remarkably, a substantial proportion of infected individuals, approximately 70% to 80% of women and 50% of men, remain asymptomatic, underscoring the paramount importance of laboratory-based diagnostic methods. In this context, immunochromatography stands out as a widely employed technique for the detection of Chlamydia trachomatis in clinical settings.This method is favored for its simplicity and expeditious results, distinguishing it from the relatively time-consuming culture-based approach and nucleic acid sequence-based amplification.

Gonorrhoea: Gonorrhoea is a sexually transmitted disease caused by the bacterium Neisseria gonorrhoeae. Gonorrhoea is one of the most common infectious bacterial diseases and is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. The causative organism can infect the throat, producing a severe sore throat. It can infect the anus and rectum, producing a condition called proctitis. With females, it can infect the vagina, causing irritation with drainage (vaginitis). Infection of the urethra may cause urethritis with burning, painful urination, and a discharge. When women have symptoms, they often note vaginal discharge, increased urinary frequency, and urinary discomfort. The spread of the organism to the fallopian tubes and abdomen may cause severe lower abdominal pain and fever. The average incubation for Gonorrhoea is approximately 2 to 5 days, following sexual contact with an infected partner. However, symptoms may appear as late as 2 weeks. A preliminary diagnosis of Gonorrhoea can be made at the time of examination in women, Gonorrhoea is a common cause of pelvic inflammatory disease (PID). PID can lead to internal abscesses and long-lasting, chronic pelvic pain PID can damage the fallopian tubes enough to cause infertility or increase the risk of ectopic pregnancy.

PRINCIPLE

The kit is a qualitative, lateral flow immunoassay for the detection of Gonorrhoea and Chlamydia antigens from a female vaginal swab sample.In the test, antibody specific to the Gonorrhoea/Chlamydia antigens is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhoea/Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Gonorrhoea/Chlamydia on the membrane, generating a color line in the test region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result to serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS AND COMPONENTS

CONPONENT	1 TEST	2 TESTS	5 TESTS
Test Cassette	1	2	5
Extraction Buffer Tube A	1	2	5
Extraction Buffer Tube B	1	2	5
Sterile Swab	1	2	5
Bio-hazard Bag	1	2	5
Instruction For Use	1	1	1

STORAGE AND STABILITY

- Store the kit as packaged in the sealed pouch at a temperature of 2~30℃. The kit remains stable within the expiration date printed on the labeling.
- Once the pouch is opened, the test should be used within 15 minutes. Prolonged exposure to hot and humid environments can cause product deterioration.
- The lot and the expiration date are printed on the label or packaging.

LIMITATIONS

1. The results of the reagent only demonstrated the presence of Chlamydia or Gonorrhoea antigen in the specimen, which is not the only basis for clinical diagnosis and treatment. Chlamydia or Gonorrhoea antigen may still be retained a short term after the treatment.
2. Test is presumptive screening only and you must consult medical practitioner for confirmatory testing of positive results by a laboratory test and for advice regarding treatment if required.
3. When test result is negative and if infection is still suspected, medical Professional should be consulted for confirmatory laboratory testing.
4. False negative results may occur due to incorrect specimen collection.
5. A positive result cannot necessarily determine whether a person is infectious.
6. Each test can only be used once.
7. Test kit may not detect the bacterium Chlamydia trachomatis acquired in the last 60 days, and it is recommended to consult a medical practitioner if exposure may have occurred during this time.
8. Test kit may not detect the bacterium Neisseria gonorrhoea acquired in the last 10 days, and it is recommended to consult a medical practitioner if exposure may have occurred during this time.

CLINICAL STUDY PERFORMANCE

The Chlamydia & Gonorrhoea Rapid Test (For Female) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. results were confirmed by the gold standard PCR test. In this study for Chlamydia, test kit correctly identified 200 of 202 positive results and correctly identified 203 of 203 negative results. Similarly for Gonorrhoea, test kit correctly identified 229 of 231 positive results, and correctly identified 210 of 210 negative results.

For Chlamydia:

Method		PCR Test		Total Results
Chlamydia & Gonorrhoea Rapid test (For Female)	Results	Positive	Negative	
	Positive	200	0	200
	Negative	2	223	225
Total Results		202	223	425
Clinical sensitivity	99.01%			
Clinical specificity	100.00%			
Accuracy	99.53%			

For Gonorrhoea:

Method		PCR Test		Total Results
Chlamydia & Gonorrhoea Rapid test (For Female)	Results	Positive	Negative	
	Positive	229	0	229
	Negative	2	210	212
Total Results		231	210	441
Clinical sensitivity	99.13%			
Clinical specificity	100.00%			
Accuracy	99.55%			

USABILITY STUDY PERFORMANCE

The Chlamydia & Gonorrhoea Rapid Test (For Female) has been self-tested and evaluated by 440 lay users, including both symptomatic and asymptomatic individuals. results were confirmed by the gold standard PCR test. In this study for Chlamydia, test kit correctly identified 106 of 106 positive results and correctly identified 114 of 114 negative results. Similarly for Gonorrhoea, test kit correctly identified 110 of 111 positive results, and correctly identified 109 of 109 negative results.

For Chlamydia:

Method		PCR Test		Total Results
Chlamydia & Gonorrhoea Rapid test (For Female)	Results	Positive	Negative	
	Positive	106	0	106
	Negative	0	114	114
Total Results		106	114	220
Clinical sensitivity	100.00%			
Clinical specificity	100.00%			
Accuracy	100.00%			

For Gonorrhoea:

Method		PCR Test		Total Results
Chlamydia & Gonorrhoea Rapid test (For Female)	Results	Positive	Negative	
	Positive	110	0	110
	Negative	1	109	110
Total Results		111	109	220
Clinical sensitivity	99.10%			
Clinical specificity	100.00%			
Accuracy	99.55%			

ANALYTIC PERFORMANCE

Limit of Detection(LoD)

The minimum detection limit of Chlamydia & Gonorrhoea Rapid test (For Female) is $3x10^5$ CFU/mL for Gonorrhoea and $2x10^4$ CFU/mL for Chlamydia.

Cross-Reactivity

The cross-reactivity of-the kit was evaluated. The results showed no cross reactivity with the following samples:Acinetobacter calcoaceticus, Pseudomona aeruginosa, Proteus mirabilis, Acinetobacter spp, Neisseria meningitides, Enterococcus faecalis,Salmonella choleraesius, Group B/C Streptococcus, Enterococcus faecium, Candida albicans, Hemophilus influenzae, Staphylococcus aureus, Proteus vulgaris, Branhamella catarrhalis, Klebsiella pneumoniae, Gardnerella vaginalis, Human immunodeficiency virus (HIV), Human papillomavirus (HPV). Herpes Simplex Virus (HSV) and Treponema pallidum.

Interference substances

Interference of the following substances were evaluated and no interfer-encewas-noted: 50μL/mL whole blood, 10mg/mL mucin, 50μL/mL urine, 5mg/mL Penicillin (suppository), 5mg/mL Miconazole (suppository), 5mg/mL Tinidazole (gel), 5mg/mL Metronidazole (gel), 20μL/mL Jieeryin (wash solution).

Variants

Test kit can detect the following type of variants for Chlamydia tracho-matis and Neiserria gonorrhoeae:
Chlamydiatra chomatis Serovar D
Chlamydiatra chomatis Serovar H
Chlamydiatra chomatis Serovar I
Chlamydiatra chomatis Serovar F
Neisseria gonorrhoeae (Zopf) Trevisan
Neisseria gonorrhoeae strain NCTC 8375 [B 5025]

PRECAUTIONS

It is important that safe sex practice is followed at all times, particularly during pregnancy, and for individuals engaging in high-risk behaviors must undergo regular testing for other sexually transmitted infections and blood borne viruses.

- For IN VITRO diagnosis only.
- Do not use after the expiration date.
- Components from difference lots must not be mixed or used together.
- The result is considered invalid after 20 minutes.
- The intensity of the quality control line does not indicate a problem with the test quality. A clearly visible test result confirms a proper test procedure.
- After use, handle all specimens and reagents with the same precautions as infectious agents, as they are considered potentially hazardous. Use the provided bio-hazard bag for disposal.
- A negative or positive result obtained when using a self-test to detect one sexually transmitted infection does not preclude infection from other sexually transmitted infections or the presence of other conditions.
- Handle test kit solutions with care, not to spill. If in contact with skin wash off with water immediately. If in eyes, rinse with plenty of water.
- Kit components are potential choking hazard. Keep out of reach of children when in use and after use.
- If you are pregnant or suspect pregnancy, please consult a healthcare provider for advice before using the test kit.
- Positive results in pregnant women can cause anxiety and hence it is important that health advice from physician is taken before use of the test kit.

MEDICAL DEVICE INCIDENT REPORT

You can contact the TGA to report performance or usability issues via the UsersMedical Device Incident Reportemail irisahealth.govau or call 1800809361.

SUPPORT SERVICES

ACT Canberra Sexual Health Centre.
Phone: (02) 51242184
Website:www.health.act.gov.au/cshc

SW Phone:1800 451 624
Website:ww.shil.nsw.gov.au

NT Clinic 34
Phone: 08 8999 2678 - Danwin
Website: https://nt.govau/welbeing/hospital-health-services/clinic34

QLD Queensland Health
Phone:13HEALTH (13 43 25 84)
Website https://www.health.ld.govau/clinical-practice/guidelinesprocedures/sex-health

SA Shine SA
Phone:1300794584
Website: wwwshinesaorg.au

VIC Sexual Health Victoria
Phone:1800013952
Website: www.shvic.org.au

INDEX OF SYMBOLS

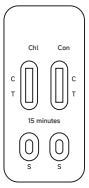
	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Keep away from sunlight
2℃-30℃	Store between 2-30˚C		Keep dry
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
LOT	Batch code		Manufacturer
	Contains sufficient for <n> tests	REF	Catalogue number

Hangzhou Fanttest Biotech Co.,Ltd.
Room 201, Building 1, No. 37-3, Futang Road, Tangqi Town, Linping District, Hangzhou City, Zhejiang Province.311106.P.R.Chin
E-mail: info@fanttest.com Tel: +86 571 86337555

Australia Sponsor
BIOTOP Pty Ltd
Unit 722368 Sussex St Sydney NSW
Customer Support Line: 02 7908 9566
E-mail: info@biotop6.com Website: www.biotop6.com

Code:XXXXX
Version No.: XXX
Effective Date:XXXXX

COMPONENTS PROVIDED



Test Cassette


Extraction Buffer Tube A


Extraction Buffer Tube B


Sterilised Swab


Bio-hazard Bag


Instructions For Use

Components required but not provided:

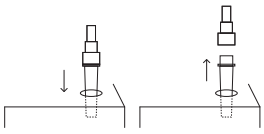

Clock or Timer


Toilet Paper

TEST PROCEDURE

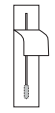

Wash or clean your hands and make sure they are dry before starting the test.

01


Carefully place the Buffer A tube into the hole provided on the kit box.

Open the lid.

02


Pull open the swab packaging at the marked point and remove the swab.


DO NOT TOUCH the soft head of swab.

03

Use toilet paper to clean the excess mucus outside the vagina before specimen collection.

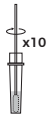
04

With care, insert the swab (only **till the soft head of the swab**) into the vagina.


Rotate the swab several times, allowing it to remain in place for a minimum of 5-10 seconds before withdrawal.


Stay for 5-10 seconds

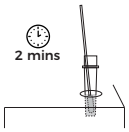
05



Insert the sampled swab into Buffer A tube and dip the tip into the tube. Ensure the tip is fully submerged in the liquid.

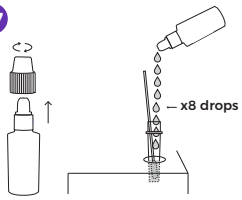
Rotate the swab tip 10 times along the inner wall of the buffer tube.

06



Let stand for 2 minutes.

07

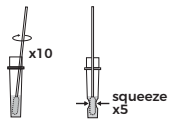


Kindly remove the cap from the droplet nozzle of Buffer B.

Add 8 drops of Buffer B into the Buffer A solution tube.

Ensure that 8 drops are added. Too much or too little buffer can affect the accuracy of the test.

08



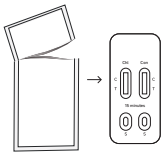
Rotate the swab tip 10 times and squeeze the tip of the swab 5 times along the inner wall of the tube to keep as much liquid in the bottle as possible.

09

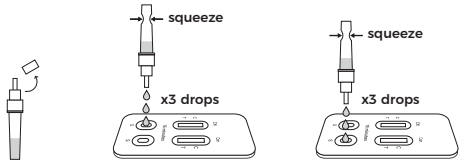
Screw on and tighten the lid of the buffer tube.

Then shake the tube vigorously to mix the specimens and the buffer liquid.

10

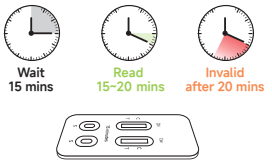

Open the foil pouch and take out the test cassette. Place it on a flat and clean surface.

11



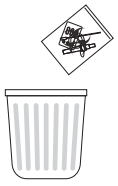
Unscrew the cap, and add 3 drops of the buffer to each specimen wells.

12



Set a timer and wait for 15 minutes. Interpret the results within a 15-20 minutes time frame.

13


Please dispose of all parts of the test kit and place them in the biohazard bag.

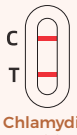
If there are local regulations, please follow them.

14


Wash your hands thoroughly after completing the test.

POSITIVE

Chlamydia



Chlamydia Positive

Gonorrhoea

Gonorrhoea Positive

A line appears at both Control region (C) and Test region (T).
The shade of the lines may vary. However, even if a faint or weak line appears, it should be considered a positive result.

If you have a Positive result, you must consult a medical practitioner for confirmatory testing of positive results by a laboratory test and for advice regarding treatment if required.

NEGATIVE

Chlamydia

Chlamydia Negative

Gonorrhoea

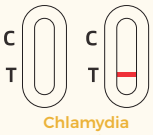
Gonorrhoea Negative

Only Red lines appear in the Control regions (C), and No line in the Test regions (T).

Negative results may not mean that you are not infectious and if symptoms persist, seek medical assistance.

INVALID

Chlamydia



Chlamydia Invalid

Gonorrhoea

Gonorrhoea Invalid

When No Control line (C) appears in the Control region for either or both tests, the results are considered invalid. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the Control line (C) failure.
Review the test procedure and repeat the test using a new test device.

Scan the QR code or visit our website for instructional video, product information and IFU:

https://www.biotop6.com/fanttest-at-home-syphilis-self-test-cassette-kit/

Customer Support help line
02 7908 9566
Customer Service hours:
9 AM ~ 8 PM, 7 Days. ~ UTC+10